DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 8, 2015

CareRay Digital Medical System Co., Ltd.
% Jamie Ku
Official Correspondent
Compass Innovations, Inc.
3001 Winchester Blvd, Suite 3
CAMPBELL CA 95008

Re: K141488
Trade/Device Name: CareView 1800R X-ray Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 13, 2015
Received: August 17, 2015

Dear Jamie Ku:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141488

Device Name
CareView 1800R X-ray Flat Panel Detectors

Indications for Use *(Describe)*
CareView 1800R X-ray Flat Panel Detectors is indicated for digital imaging solution designed for providing general radiographic system in all general purpose diagnostic procedures. CareView 1800R X-ray Flat Panel Detectors is a component of a digital imaging system. Properly integrated into a completed X-ray system, the detector enables the digital X-ray imaging intended for medical application.
This product is not intended for mammography applications and dental X-ray applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

August 13, 2015

2. Submitter's Information [21 CFR807.92 (a) (1)]

Company Name:	CareRay Digital Medical System Co., Ltd.
Company Address:	Suite 201, Building A2, BIOBAY, 218 Xing Hu Street, SuZhou Industrial Park, SuZhou 215123, P.R.China
Contact Person:	Ms. Ding
Phone Number:	(86) 512-86860288
Fax Number:	(86) 512-86860388
E-mail:	yl.ding@careray.com

3. Trade Name, Common Name, Classification [21 CFR807.92(a)(2)]

Trade Name:	X-ray Flat Panel Detectors
Model Name:	CareView 1800R
Classification Name:	Stationary X-ray system
Regulation Number:	21 CFR 892.1680
Regulatory Class:	Class II
Product Code:	MQB

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicates within this submission are as follows:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-40EG
Classification Name:	Stationary X-ray system
Regulation Number:	21 CFR 892.1680
Regulatory Class:	Class II

Product Code: MQB

FDA 510(k) #: K050987

5. Description of the Device [21 CFR 807.92(a)(4)]

CareView 1800R X-ray Flat Panel Detectors supports the single frame mode, with the key component of TFT/PD image sensor flat panel of active area: 43cm×43cm. The sensor plate of CareView 1800R X-ray Flat Panel Detectors is direct-deposited with CsI scintillator to achieve the conversion from X-ray to visible photon. The visible photons are transformed to electron signals by diode capacitor array within TFT panel, which are composed and processed by connecting to scanning and readout electronics, consequently to form a panel image by transmitting to PC through the user interface.

The major function of the CareView 1800R X-ray Flat Panel Detectors detector is to convert the X-ray to digital image, with the application of high resolution X-ray imaging. This detector is the key component of DR system, enables to complete the digitalization of the medical X-ray imaging with the DR system software.

6. Intended Use [21 CFR 807.92(a)(5)]

CareView 1800R X-ray Flat Panel Detectors is indicated for digital imaging solution designed for providing general radiographic system in all general purpose diagnostic procedures. CareView 1800R X-ray Flat Panel Detectors is a component of a digital imaging system. Properly integrated into a completed X-ray system, the detector enables the digital X-ray imaging intended for medical application.

This product is not intended for mammography applications and dental X-ray applications.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Item	**Proposed Device: CareView 1800R X-ray Flat Panel Detectors**	**Predicate Device: CXDI-40EG**
510(K) Number	To be assigned	K050987
Intended Use	The CareView 1800R X-ray Flat Panel Detectors is indicated for digital imaging solution designed for providing general radiographic system in all general purpose diagnostic procedures. CareView 1800R X-ray Flat Panel Detectors is a component of a digital imaging system. Properly integrated into a	DIGITAL RADIOGRAPHY CXDI-40EG provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

	completed X-ray system, the detector enables the digital X-ray imaging intended for medical application. This product is not intended for mammography applications and dental X-ray applications.	
Classification Name	Stationary X-ray system	Stationary X-ray system
Product Code	MQB	MQB
Regulation Number	21 CFR 892.1680	21 CFR 892.1680
Panel	Radiology	Radiology
Class	II	II
X-ray Absorber	CsI Scintillator	GOS
Installation Type	Stationary, permanently installed	Stationary, permanently installed
Readout Mechanism	Thin Film Transistor	Thin Film Transistor
Detector Size	492 x 492 x 33.5 mm	550 x 550 x 67.5 mm
Detector Weight	13 kg	20 kg
Pixel Array	2816×2816	2688 x2688
Active Area	43cm×43cm	43cm×43cm
Pixel Pitch	154μm	160μm
ADC Digitization	16 bit	14 bit
Power Consumption	~36 W	Max.200 VA
Modulation Transfer Function (MTF)	1 lp/mm (70±3)% 2 lp/mm (42±3)% 3 lp/mm (23±3)%	1 lp/mm 68% 2 lp/mm 38% 3 lp/mm 18%
Detective Quantum Efficiency (DQE)	DQE at 5 μGy 0 lp/mm (63±3)% 1 lp/mm (45±3)% 2 lp/mm (33±3)% 3 lp/mm (20±3)%	DQE at 5 mR 0 lp/mm 37% I lp/mm 34% 2 lp/mm 24% 3 lp/mm 12%
Power Supply	Voltage: 100-250 VAC	Voltage: 100V, 120V, 230/240 V
	Frequency: 50/60 Hz	Frequency: 50/60 Hz
Operating Condition	Temperature: 5 ~ 35˚C	Temperature: 5~35℃
	Relative humidity: 30~75% RH	Relative humidity: 30~75%
	Air pressure: 700hPa~1060hPa	Air pressure: 700hPa ~1060hPa
Storage Condition	Temperature: -20~55 ˚C	Temperature: -30~60 ˚C
	Relative humidity: 10~90%RH	Relative humidity: 10~60%
	Air pressure: 700hPa~1060hPa	Air pressure: 700hPa ~1060hPa

8. System requirements to operate with other radiographic system components

1) Recommended Generator Specification:

Energy range: 40~150kVp

mA range: 10~1000mA (depending on the generator power)

ms range: 10~6300ms to produce 0.1~1000mAs (depending on the generator power)

Note: To our best knowledge, the detector is compatible with the X-ray generators with the specifications described above. If you have questions regarding the compatibility issue for other generators, please contact your distributor or CareRay.

2) Application Program Interface (API) for system integration manufacturer

Peripheral hardware: CareView detector connected via wired communication.

CPU: Intel (R) Core (TM) 2 Duo, 2.93GHz or above

RAM: 2 GB or higher

Hard disk: 160 GB or higher

Monitor: 1280 x 1024 or higher

OS: Windows XP or Windows 7

Development environment: MS Visual Studio 2005

3) X-ray exposure mode

The synchronous connection mode is the signal transfer mode between the X-ray generator which sends the X-ray and the detector which receives the X-ray.

CareView 1800R supported typical sync mode contains external sync, manual sync mode.

The detector can't provide feedback to the generator to terminate the x-ray exposure.

9. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92(b)(2)]

- Electrical safety and EMC testing

  Electrical, mechanical, environmental safety and performance testing according to IEC/ES 60601-1 was performed, and EMC testing was also conducted in accordance with IEC/EN 60601-1-2. All test results are satisfactory. Section 201.7.2.7, 201.7.9.1, 201.7.9.2.1.103 and 203.4.1 of IEC 60601-2-54 were also conducted.

- Nonclinical considerations

  The following non-clinical studies have been performed and the results have shown that the CareView 1800R X-ray flat panel detector is substantially equivalent to the predicate devices on the Market (CXDI-40EG).

-Detective quantum efficiency (DQE), Quantum limited performance, Modulation transfer function (MTF), Effects of aliasing, Sensitivity linearity, Lag(Erasure thoroughness), Change in detection sensitivity, Dose requirement and reciprocity changes, Stability of device characteristics with time, Uniformity of device characteristic, Noise power spectrum(NPS), Spatial resolution, Image Acquisition time, & Black level

- Clinical considerations

  A concurrence study of 30 clinical images was conducted to compare the performance of the CareView 1800R to that of the predicate device (K050987).

  Clinical images were provided; these images were not necessary to establish substantial equivalence based on the superior performance in comparison to the predicate based on laboratory testing and based on the use of a detector scintillator material that is already on the marketplace; however, they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.

  There was no significant difference between the images of the CareView 1800R and those of the predicate device.

10. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, the CareView 1800R X-ray flat panel detector is substantially equivalent to predicate device CXDI-40EG (K050987). Both propose and predicate devices are same or very similar in the intended use, the design principle, the applicable standards and specification. Some characteristics, for example, the detector size, pixel pitch, weight and ADC digitization, X-ray absorber, storage condition are different. However the test reports in this submission documents provide demonstration that these differences do not raise any new questions of safety and effectiveness. Therefore, CareRay Digital Medical System Co., Ltd. concludes the CareView 1800R X-ray flat panel detector is substantially equivalent with the predicate device CXDI-40EG (K050987) of Canon Inc.